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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,703	04/21/2004	Edward Wells Knowlton	KNW-0019	5381

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Goodwin Procter LLP
Attn: Patent Administrator
135 Commonwealth Drive
Menlo Park, CA 94025-1105

EXAMINER	
ROANE, AARON F	

ART UNIT	PAPER NUMBER
3769	

MAIL DATE	DELIVERY MODE
11/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/828,703	KNOWLTON, EDWARD WELLS	
	Examiner	Art Unit	
	Aaron Roane	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5 and 7-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5 and 7-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 February 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-39 of copending Application No. 10/813,980. Although the conflicting claims are not identical, they are not patentably distinct from each other because they entail the same set of steps.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

Claims 7, 8 and 12 are objected to because of the following informalities: claims 7, 8 and 12 recite in line 1 of each claim "the method of claim I", wherein the examiner has interpreted "I" as "1" in order to provide an examination and search.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 7-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Knowlton (USPN 6,350,276).

Regarding claims 1, 7 and 15, Knowlton discloses a method of treating a target tissue site, the method comprising: using an energy delivery device to apply a combination of energy treatments delivered to different tissue depths; identifying/selecting the tissue site based on a tissue profile or condition/deformity of the tissue site (col. 2, lines 19-46, col. 12, line50-67, col. 13, 35-47 and col. 14, lines 19-54); delivering energy to the tissue site

at a first depth to achieve a first tissue effect using an energy delivery device, wherein the first tissue effect is a two dimensional tightening of the skin surface (col. 2, line 20 through col. 3, line 28); delivering energy to the tissue site at a second depth to achieve a second tissue effect using an energy delivery device, wherein the second tissue effect is a three dimensional tissue repositioning or inward contouring (col. 2, line 20 through col. 3, line 28); and remodeling at least a portion of tissue at the tissue site (col. 2, lines 19-46, col. 8, lines 11-30 and claim 1). One energy deliver is radio frequency (RF a type of electromagnetic energy) which delivers energy to at least a first or second depth, see col. 6, lines 5-48 and col. 7, line 52 through col. 8, line 30 and col. 13, line 18 through col. 21, line14.

Regarding claims 2 and 16, Knowlton further discloses the tissue site is selected based on an amount of convexity at the tissue site or an image of the tissue site, see col. 12, lines 1-3.

Regarding claims 3, 8, 17 and 18, Knowlton disclose the claimed invention, see col. 6, lines 5-48, col. 7 and 8.

Regarding claim 9, Knowlton further discloses delivering a pattern of energy applications to the tissue site using the energy delivery device; and producing a plurality of thermal adhesions or lesions wherein the plurality of adhesions or lesions is substantially continuous or at least partially overlapping, see col. 16, lines 54-67.

Regarding claim 10, Knowlton discloses delivering a vectored force to the tissue site, see col. 8, lines 11-30.

Regarding claim 11, Knowlton further discloses cooling a layer of tissue or a surface layer of tissue of at least a portion of the tissue site, see col. 4, line 55 through col. 5, line 15.

Regarding claim 12, Knowlton further discloses producing a reverse thermal gradient within at least a portion of the tissue site, see col. 5, lines 52-59.

Regarding claim 13, Knowlton discloses producing a reverse thermal gradient within at least a portion of the tissue site, see col. 10, lines 1-3.

Regarding claim 14, Knowlton further disclose substantially preserving at least a portion of a surface, a tissue layer or an epidermal layer at or adjacent the tissue site, see entire disclosure, particularly col. 2, 8 and 14.

Regarding claim 19, Knowlton further disclose controlling at least one of dose or the depth of energy delivery responsive to the identified deformity, see col. 7, line 31-51.

Regarding claim 20, Knowlton further disclose the dose or depth or depth of energy delivery is controlled by at least one of the selection of electrode size, power, pre-cooling period, cooling period, or energy delivery time, see col. 7, line 31-51.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Knowlton (USPN 6,350,276) (Knowlton I) as applied to claim 1 above, and further in view of Knowlton (USPN 6,377,854) (Knowlton II).

Regarding claim 5, Knowlton I discloses the claimed invention except for the contraction of fibrous septae. Knowlton II discloses a RF treatment device and teaches that the RF treatment device applies energy to soft tissue in order to "contract collagen in fibrous septae in subcutaneous fat layers underlying the skin surface so as to modify a structure of the underlying tissue such that soft tissues in the subcutaneous fat layers are tightened and fat is reduced in lipocytes in the subcutaneous fat layers," see claim 1. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to

modify the invention of Knowlton I, as taught by Knowlton II, to "contract collagen in fibrous septae in subcutaneous fat layers underlying the skin surface so as to modify a structure of the underlying tissue such that soft tissues in the subcutaneous fat layers are tightened and fat is reduced in lipocytes in the subcutaneous fat layers."

Response to Arguments

Applicant's arguments filed 7/25/2008 have been fully considered but they are not persuasive. The examiner will address each argument/remark in turn.

Beginning on page 6, last paragraph, Applicant asserts that amended claim 1 which recites "using an electromagnetic energy delivery device to apply a combination of energy treatments delivered to different tissue depths" is not anticipated by the Knowlton I patent above. This is clearly incorrect, as claim 7 recites RF, microwave, laser or ultrasound energy delivery devices and was previously rejected by Knowlton I, who discloses a RF delivery device. It is unclear why Applicant has missed this fact. The examiner has interpreted claim 1 to be directed to a RF energy delivery device to apply a combination of energy treatments delivered to different tissue depths which delivers RF energy to one depth and thermal energy to a second depth. If Applicant is attempting to claim an electromagnetic device which delivers RF energy having one particular pattern to one tissue depth and RF energy having a different particular pattern, then Applicant should explicitly do so. At present, the claim language does not preclude the present

interpretation by the examiner, such that the electromagnetic energy delivery device delivers RF energy to one tissue depth and thermal energy to a second tissue depth.

Due to Applicant's amendment, a new grounds of rejection has been presented, although it is very similar to the previously made rejection. This office action makes it clear that RF is a form of electromagnetic energy.

This action is made FINAL.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 8:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron Roane/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit 3769